Summary of Product Characteristics

HILDREM-CH™ CREAM/CURAPEL

1. NAME OF THE MEDICINAL PRODUCT

HILDREM-CH™ CREAM/ CURAPEL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gm contains:

Silver Sulfadiazine USP	1% w/w
Chitosan Hydrochloride BP	2 % w/w
Cream base	QS

3. PHARMACEUTICAL FORM

Off-White coloured smooth cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

HILDERM-CH™ /CURAPEL cream is a topical antimicrobial drug indicated as an adjunct for the prevention and treatment of wound sepsis healing in patients with second- and third-degree burns.

4.2 Posology and method of administration

The burn areas should be covered with HILDERM-CH™ /CURAPEL cream at all times. The cream should be applied once to twice daily to a thickness of approximately 1/16 inch. Whenever necessary, the cream should be reapplied to any areas from which it has been removed by patient activity. Administration may be accomplished in minimal time because dressings are not required. However, if individual patient requirements make dressings necessary, they may be used.

Reapply immediately after hydrotherapy:

Treatment with HILDERM-CH/ CURAPEL should be continued until satisfactory healing has occurred, or until the burn site is ready for grafting. The drug should not be withdrawn from the therapeutic regimen while there remains the possibility of infection except if a significant adverse reaction occurs.

4.3 Contraindications

HILDERM-CH™ / CURAPEL is contraindicated in patients who are hypersensitive to silver sulfadiazine or any of the other ingredients in the preparation.

4.4 Special warnings and precautions for use

There is potential cross-sensitivity between silver sulfadiazine and other sulfonamides. If allergic reactions attributable to treatment with silver sulfadiazine occur, continuation of therapy must be weighed against the potential hazards of the particular allergic reaction.

Fungal proliferation in and below the eschar may occur. However, the incidence of clinically reported fungal superinfection is low.

The use of silver sulfadiazine in some cases of glucose-6-phosphate dehydrogenase-deficient individuals may be hazardous, as hemolysis may occur.

If hepatic and renal functions become impaired and elimination of drug decreases, accumulation may occur and discontinuation of HILDERM-CH/ CURAPEL should be weighed against the therapeutic benefit being achieved.

Long-term dermal toxicity studies of 24 months duration in rats and 18 months in mice with concentrations of silver sulfadiazine three to ten times the concentration in silver sulfadiazine cream 1 % revealed no evidence of carcinogenicity.

4.5 Interaction with other medicinal products and other forms of interaction

Interactions if observed are non-fatal. It may interact with topical proteolytic enzymes and cyclosporine.

4.6 Pregnancy and lactation

Because sulfonamide therapy is known to increase the possibility of kernicterus, silver sulfadiazine and chitosan cream should not be used on pregnant women approaching or at term, on premature infants, or on new-born infants during the first 2 months of life.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Following side effects may observed:

Blood dyscrasias including agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, and hemolytic anemia; dermatologic and allergic reactions, including Stevens- Johnson syndrome and exfoliative dermatitis; gastrointestinal reactions; hepatitis and hepatocellular necrosis; CNS reactions; and toxic nephrosis.

4.9 Overdose

No Information Provided.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Silver sulfadiazine has broad antimicrobial activity. It is bactericidal for many gram- negative and gram-positive bacteria as well as being effective against yeast.

Silver sulfadiazine inhibits bacteria that are resistant to other antimicrobial agents and that the compound is superior to sulfadiazine. Silver sulfadiazine acts only on the cell membrane and cell wall to produce its bactericidal effect.

Chitosan is a linear polysaccharide of ß (1,4) linked D-glucosamine. It is a potential biopolymer because of it's unique properties like non-toxicity, biodegradability & biocompatibility. Chitosan enhances fibroplasia which leads to repair & maturation of injured tissue promotion action. So fibroplasia enhancer chitosan is combines with antibacterial silver sulfadiazine which act synergistically with chitosan so that wound healing is very fast.

5.2 Pharmacokinetic properties

When applied topically it releases silver ions and free sulfadiazine. Minimal quantity of sulfadiazine and chitosan may be absorbed systemically.

5.3 Preclinical safety data

Nonclinical data reveal no special hazard for humans based on studies of safety pharmacology, genotoxicity and toxicity to reproduction.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipient(s)

Light liquid paraffin, Cetostearyl alcohol, Cetomacrogol-1000, Methyl paraben, Disodium EDTA, butylated hydroxytoluene, Glycerin and Purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in a dry place below 30°C.Protect from light.

6.5 Nature and contents of container

30 g Aluminium tube packed in a carton along with a leaflet / 250 gm Jar

6.6 Special precautions for disposal and other handling

No special requirements

7. MARKETING AUTHORISATION HOLDER

MA Holder:

Bliss GVS Pharma Ltd.

102, Hyde Park, Saki Vihar Road, Andheri East Mumbai 400072. India.